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21559 7590 12/15/2009

CLARK & ELBING LLP
101 FEDERAL STREET
BOSTON, MA 02110

EXAMINER	
KOSAR, AARON J	
ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 12/15/2009

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,659	05/26/2006	Andrea Pastorello	50294/018001	5027

TITLE OF INVENTION: COMPOSITE STRUCTURES CONTAINING HYALURONIC ACID THE DERIVATIVES THEREOF AS NEW BONE SUBSTITUTES AND GRAFTS

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	$1510	$300	$0	$1810	03/15/2010

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PTOL-85 (Rev. 08/07) Approved for use through 08/31/2010.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
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INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

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I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

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10/580,659	05/26/2006	Andrea Pastorello	50294/018001	5027

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nonprovisional	NO	$1510	$300	$0	$1810	03/15/2010

EXAMINER	ART UNIT	CLASS-SUBCLASS
KOSAR, AARON J	1651	424-423000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

❑ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

❑ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) the names of up to 3 registered patent attorneys or agents OR, alternatively,

(2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 _____

2 _____

3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ❑ Individual ❑ Corporation or other private group entity ❑ Government

4a. The following fee(s) are submitted:

❑ Issue Fee

❑ Publication Fee (No small entity discount permitted)

❑ Advance Order - # of Copies _____

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**

❑ A check is enclosed.

❑ Payment by credit card. Form PTO-2038 is attached.

❑ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)

❑ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27.

❑ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 10 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 10 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

PTOL-85 (Rev. 08/07) Approved for use through 08/31/2010.

Notice of Allowability	Application No.	Applicant(s)	
	10/580,659	PASTORELLO ET AL.	
	Examiner	Art Unit	
	AARON J. KOSAR	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *communication of 7/27/2009*.

2. ☒ The allowed claim(s) is/are *1, 2, 4-17, 19, 20, 33-53, 61, 63, and 83-88*.

3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☒ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

/Aaron J Kosar/
Examiner, Art Unit 1651

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 27, 2009 has been entered.

Claims 1, 2, 4-17, 19, 20, 33-53, 61, 63, and 83-88 have been examined on the merits and found allowable (as amended within the Examiner's Amendment below).

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Applicant's representative, Susan Michaud, on December 4, 2009.

In the Claims:

Claims 3, 18, 21-32, 54-60, 62, and 64-82 have been canceled (as shown below).

The claims have been amended to read as follows:

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1. An osteoconductive and osteoinductive multilayer composite material comprising:

(I) an inner matrix composite material comprising:

(i) hyaluronic acid and a hyaluronic acid derivative, wherein said hyaluronic acid derivative is in a form selected from the group consisting of a non-woven material, a woven material, a compact membrane or film, and a perforated membrane or film; and

(ii) demineralised bone and/or biocompatible and biodegradable ceramic and/or bone of autologous or allogenic or animal origin, and

(II) at least two layers, each layer comprising a hyaluronic acid derivative,

wherein the hyaluronic acid derivatives in (I)(i) and (II) are each selected from the group consisting of:

(a) an ester of hyaluronic acid,

(b) an inner ester of hyaluronic acid,

(c) an amide of hyaluronic acid,

(d) an O-sulphated derivative of hyaluronic acid,

(e) a deacetylated derivative of hyaluronic acid, and

(f) a percarboxylated derivative of hyaluronic acid, and

wherein said at least two layers (II) are superimposed on said inner matrix (I) thereby sandwiching said inner matrix (I) between said layers (II).

2. The multilayer composite material of claim 1, wherein the hyaluronic acid in (i) is a hyaluronic acid salified with an organic or inorganic base.

3. (Canceled)-

4. The multilayer composite material of claim 1, wherein said hyaluronic acid derivative is a benzyl ester of hyaluronic acid.

5. The multilayer composite material of claim 4, wherein the benzyl ester has a degree of esterification of from 50% to 100%.

6. The multilayer composite material of claim 5, wherein the benzyl ester has a degree of esterification of from 75% to 100%.

7. The multilayer composite material of claim 1, wherein said hyaluronic acid derivative is the hyaluronic acid inner ester having an esterification degree lower than 20%.

8. The multilayer composite material of claim 7, wherein the hyaluronic acid inner ester has an esterification degree between 0.05% and 5%.

9. The multilayer composite material of claim 1, wherein said hyaluronic acid derivative is the amide of hyaluronic acid having an amidation degree of lower than or equal to 15%.

10. The multilayer composite material of claim 9, wherein the amidation degree is between 0.1% and 15%.

11. The multilayer composite material of claim 1, wherein said hyaluronic acid derivative is the deacetylated hyaluronic acid having a percentage of deacetylation lower than or equal to 30%.

12. The multilayer composite material of claim 1, wherein said hyaluronic acid derivative is the percarboxylated hyaluronic acid (f) having a percarboxylation degree of between 0.1% and 100%.

13. The multilayer composite material of claim 12, wherein said percarboxylation degree is between 25% and 75%.

14. The multilayer composite material of claim l, wherein the biocompatible and biodegradable ceramics are selected from the group consisting of hydroxyapatite, anhydrous tribasic calcium phosphate, and calcium sulphate.

15. The multilayer composite material of claim 1, wherein the demineralised bone is a partially or completely demineralised bone matrix..

16. The multilayer composite material of claim 1, wherein the hyaluronic acid derivative has a molecular weight of between 200 and 750 KD.

17. The multilayer composite material of claim 1, wherein the hyaluronic acid derivative in the inner matrix (I) is in a form selected from the group consisting of a sponge, a paste, a gel, a granule, and a powder.

18. (Canceled)

19. The multilayer composite material of claim 1, wherein said at least two layers (II) comprises two layers.

20. The multilayer composite material of claim 1, wherein said at least two layers (II) comprises three layers.

21-32. (Canceled)

33. The multilayer composite material of claim 1, wherein the inner matrix (I) is in the form of a sponge consisting of the benzyl ester of hyaluronic acid having a percentage of esterification between 70% and 100%, containing inside said sponge: bone granules or powders; or granules or other three-dimensional structures containing said biodegradable ceramics; or said partially or

completely demineralised bone matrix.

34. The multilayer composite material of claim 1, further comprising a coating of said hyaluronic acid and/or derivatives thereof; said composite material in the form of a thin film and/or sponge, to favour entry, distribution, and adhesion of cells that will migrate when said cells are loaded therein.

35. The multilayer composite material of claim 1, wherein the inner matrix is in the form of a sponge formed by the inner esters of hyaluronic acid, the inner matrix containing partially or completely demineralised bone matrix; biocompatible and biodegradable ceramic; or bone in the form of granules and/or powders and of autologous or allogenic or animal origin.

36. The multilayer composite material of claim 1, wherein the inner matrix is in the form granules, spheres, powders, and/or three-dimensional structures of various shapes and sizes, the matrix consisting of biodegradable ceramics that are coated or incorporated with a layer of hyaluronic acid which is cross-linked into the inner ester of said layer of hyaluronic acid, thereby covering all the biodegradable ceramics.

37. The multilayer composite material of claim 1, wherein the inner matrix is in the form of pastes and/or gels containing demineralised bone matrix; granules or other three-dimensional structures containing biocompatible and biodegradable ceramics; or pastes and/or gels consisting of said hyaluronic acid and hyaluronic acid derivatives enclosing bone powders and/or granules that are autologous or allogenic or of animal origin.

38. The multilayer composite material of claim 1, wherein the inner matrix is in the form of fibres comprising the benzyl ester of hyaluronic acid having a percentage of esterification between 50% and 100%, the inner matrix optionally associated with other natural polymers selected from the group consisting of collagen, and cellulose, or synthetic polymers selected from the group consisting of poly-lactic, polyglycolic, and poly-caprolactone acid, and wherein said natural or synthetic polymers are in association with demineralized bone matrix and hyaluronic acid.

39. The multilayer composite material of claim 1, wherein the matrix is wetted with a solution of the hyaluronic acid ester, to compact the matrix between the layers in which said matrix is sandwiched.

40. The multilayer composite material of claim 1, wherein said matrix consists of fibres of hyaluronic acid benzyl ester having an esterification degree of 75% and in an amount in the composite material from 10% to 50%; demineralised bone matrix in an amount from 50% to 90%; and hyaluronic acid having an average molecular weight ranging from 200 to 750 KD, in an amount from 0.1% to 40%.

41. The multilayer composite material of claim 40, wherein said matrix consists of fibres of hyaluronic acid benzyl ester having an esterification degree of 75% in an amount in the composite material from 14% to 24%; demineralised bone matrix in an amount between 60% and 80%; and hyaluronic acid having an average molecular weight from 500 to 700 KD in an amount between 5% and 10%.

42. The multilayer composite material of claim 1, wherein said inner matrix is immersed in a solution to compact the matrix and to fix the matrix to the layers (II).

43. The multilayer composite of claim 42, wherein said composition further comprises a polymer selected from the group consisting of a hyaluronic acid benzyl ester with a percentage of esterification of between 55% and 100%; a fibrin glue; a photocrosslinkable polymer; and collagen.

44. The multilayer composite material of claim 1, wherein said at least two one or more layers (II) comprises hyaluronic acid ester.

45. The multilayer composite material of claim 44, wherein said hyaluronic acid is the benzyl ester having a percentage of esterification between 50% and 100%.

46. The multilayer composite material of claim 45, wherein said percentage of esterification is between 75% and 100%.

47. The multilayer composite material of claim 44, wherein the layers (II) are in the form of a non-woven material, containing fibres of the hyaluronic acid ester and optionally associated with a natural polymer selected from the group consisting of collagen and cellulose, or a synthetic polymer selected from the group consisting of poly-lactic acid, poly-glycolic acid, and poly-caprolactone acid.

48. The multilayer composite material of claim 44, wherein the layers (II) are in the form of a woven material containing fibres of the hyaluronic acid ester, optionally immersed in a solution of hyaluronic acid.

49. The multilayer composite material of claim 1, wherein the layers are in the form of a compact, perforated porous or microporous membrane or film.

50. The multilayer composite material of claim 1, further containing a pharmacologically and/or biologically active ingredient.

51. The multilayer composite material of claim 50, wherein the pharmacologically active ingredient is selected from the group consisting of
antibiotics, antineoplastics, anti-inflammatories, cytokines, vitamins, and cytotoxic, cytostatic and antiviral agents.

52. The multilayer composite material of claim 50, wherein biologically active ingredients contain trophic, osteoinductive, and/or angiogenetic factors.

53. The multilayer composite material of claim 52, wherein the trophic, osteoinductive, and/or angiogenetic factors are selected from the group consisting of bone morphogenetic protein, transforming growth factor, platelet derived growth factor, fibroblast growth factor, epidermal growth factor, insulin-like growth factor, and vascular endothelial growth factor.

54-60. (Canceled)

61. A bone substitute or graft consisting of the multilayer composite material of claim 1.

62. (Canceled)

63. The bone substitute or graft of claim 61, wherein the graft is in the form of a sandwich or bag.

64-82. (Canceled)

83. The multilayer composite material of claim 1, wherein the hyaluronic acid derivative is in the form of fibres.

84. The multilayer composite material of claim 1, wherein the inner matrix (I) is in the form of a paste.

85. The multilayer composite material of claim 1, wherein the at least two layers (II) comprise the hyaluronic acid derivative in the form of a woven material.

86. The multilayer composite material of claim 1, wherein said inner matrix (I) comprises said hyaluronic acid derivative in an amount between 10% and 50%; said demineralised bone and/or biocompatible and biodegradable ceramic and/or bone of autologous or allogenic or animal origin in an amount between 50% and 90%; and said hyaluronic acid in an amount between 0.1% and 40%.

87. The multilayer composite material of claim 86, wherein the inner matrix (I) comprises said hyaluronic acid derivative in an amount between 14% and 24%; said demineralized bone and/or biocompatible and biodegradable ceramics and/or bone of autologous or allogenic or animal origin in an amount between 60% and 80%; and said hyaluronic acid in an amount between 5% and 10%.

88. The multilayer composite material of claim 1, wherein the inner matrix (I) is in the form of a paste comprising a benzyl ester of hyaluronic acid in the form of fibres, hyaluronic acid, and demineralised bone, and wherein the at least two layers (II) comprise the hyaluronic acid derivative in the form of a woven material.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARON J. KOSAR whose telephone number is (571)270-3054. The examiner can normally be reached on Monday-Thursday, 7:30AM-5:00PM, ALT. Friday,EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Aaron J Kosar/
Examiner, Art Unit 1651

/Christopher R. Tate/
Primary Examiner, Art Unit 1655